

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

**PCT**

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 22 June 1999 (22.06.99)	
<b>International application No.</b> PCT/EP98/06294	<b>Applicant's or agent's file reference</b> B 2911 PCT
<b>International filing date (day/month/year)</b> 02 October 1998 (02.10.98)	<b>Priority date (day/month/year)</b> 02 October 1997 (02.10.97)
<b>Applicant</b> PELTONEN, Leena et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
26 April 1999 (26.04.99)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b> <p style="text-align: center; margin-top: 20px;">Catherine Massetti</p>
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PARENT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

VOSSIUS & PARTNER  
Siebertstrasse 4  
D-81675 München  
ALLEMAGNE

Date of mailing (day/month/year) 26 May 1999 (26.05.99)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference B 2911 PCT	
International application No. PCT/EP98/06294	International filing date (day/month/year) 02 October 1998 (02.10.98)
International publication date (day/month/year) 15 April 1999 (15.04.99)	Priority date (day/month/year) 02 October 1997 (02.10.97)
Applicant MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG DER WISSENSCHAFTEN E.V. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
3. An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
4. The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
02 Octo 1997 (02.10.97)	97117154.1	EP	03 May 1999 (03.05.99)
08 Octo 1997 (08.10.97)	97117398.4	EP	18 Dece 1998 (18.12.98)
12 Nove 1997 (12.11.97)	97119810.6	EP	18 Dece 1998 (18.12.98)

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer  Catherine Massetti  Telephone No. (41-22) 338.83.38
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## PATENT COOPERATION TREATY

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NOTIFICATION CONCERNING  
DOCUMENT TRANSMITTED

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as designated Office

Date of mailing (day/month/year)

26 May 1999 (26.05.99)

International application No.

PCT/EP98/06294

International filing date (day/month/year)

02 October 1998 (02.10.98)

Applicant

MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG DER WISSENSCHAFTEN E.V. et al

The International Bureau transmits herewith the following documents and number thereof:

\_\_\_\_\_ cop(ies) of priority document(s) (Rule 17.2(a))

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Catherine Massetti

Telephone No.: (41-22) 338.83.38

REC'D 18 JAN 2000

IPN

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B 2911 PCT	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) <b>FOR FURTHER ACTION</b>	
International application No. PCT/EP98/06294	International filing date (day/month/year) 02/10/1998	Priority date (day/month/year) 02/10/1997
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG ...		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  26/04/1999	Date of completion of this report  11.01.00
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  SCHEFFZYK, I  Telephone No. +49 89 2399 8602



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP98/06294

## I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

### Description, pages:

1-43 as originally filed

### Claims, No.:

1-28 as originally filed

### Drawings, sheets:

1/22-22/22 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP98/06294

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-28
Inventive step (IS)	Yes: Claims	
	No: Claims	1-28
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	28:See section VIII/4).

### 2. Citations and explanations

**see separate sheet**

## VI. Certain documents cited

### 1. Certain published documents (Rule 70.10)

and / or

### 2. Non-written disclosures (Rule 70.9)

**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/EP98/06294

SECTION V-----

Any hitherto known gene encoding a protein having the Cys4-His-Cys3 motif, such as TIF1 and the Mi-2 autoantigen, anticipates novelty of claim 1(c) and claim 6(c). Correspondingly, claims 2-5 being dependent on claim 1 are not novel either as for instance the TIF1 encoding gene exhibits the properties defined in these claims (see Le Douarin B. et al., EMBO Journal, vol. 14, no. 9, May 1995, pp. 2020-2033 (1)). Moreover, taking into account that some of the genomic DNA sequences described in Levanon D. et al., Biochemistry and Molecular Biology International, vol. 35, no. 5, April 1995, pp. 929-936 (2) cover exon 14 of presently claimed sequence encoding the protein having the sequence shown in SEQ.ID.NO. 2A the teaching of (2) also destroys novelty of claims 1(c), 4, 5, 13-25. Relating to claim 1(c) it is also noted that a nucleic acid molecule hybridizing to the nucleic acid molecule of (a) or (b) is a complementary strand which per se cannot encode a peptide co-segregating in mutated form with APECED. Therefore, this functional definition is not suitable to render claims 1(c) and 6(c) novel over for instance (1).

In addition, it is noted that due to the present wording of claims 1(a)(b) and 6(a)(b) ("a nucleic acid molecule **comprising** a nucleic acid molecule...") also the genomic DNA disclosed in Aaltonen J. et al., Nature Genetics, vol. 8, September 1994, pp. 83-87 anticipates novelty of these claims, and correspondingly, also of claims 2-4, 7-12 as the embodiments of these claims are inherently met by the genomic DNA taught in (3).

Finally, considering that claims 1-3 are not novel and having regard to the term "corresponding disease state" novelty of claims 26 to 28 also is questionable. Accordingly, claims 1-28 do not meet the requirements of Art. 33(2)(3) PCT.

SECTION VI-----

The Finnish-German Apeced Consortium, Nature Genetics (1997 December)  
17(4), 399-403

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/EP98/06294

SECTION VIII-----

- 1). In the absence of any indication concerning the hybridization conditions the term "hybridizing" used in claims 1 and 6 renders the scope of these claims unclear.
- 2). Irrespective of the fact that the term "homologue" has a well-recognized meaning in the art the use of said term renders the scope of claims 4 and 5 unclear since without an indication with respect to the percental identity between different sequences the expression "homologue" only indicates a certain similarity between two sequences.
- 3). Considering that presently claimed peptide is a molecule with multiple functions (see page 6 of present application "in a preferred embodiment....) the expression "loss of function or gain of function" written in claim 7 without a reference which characterise the precise function meant renders the scope of claim 7 completely unclear. Correspondingly, the scope of claims 11 and 12 also is rather obscure.
- 4). Concerning claims 1(c) and 6(c) it is noted that a nucleic acid molecule that hybridizes to a nucleic acid molecule encoding a protein cannot encode a protein since it is a (-) strand.
- 5). For the assessment of the present claim 28 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.





## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup>:</b> <b>C12N 15/12, C07K 14/47, A61K 38/17, 39/395, G01N 33/68, C12Q 1/68, C07K 16/18, A61K 48/00</b>	<b>A3</b>	<b>(11) International Publication Number:</b> <b>WO 99/18197</b> <b>(43) International Publication Date:</b> 15 April 1999 (15.04.99)
<b>(21) International Application Number:</b> PCT/EP98/06294 <b>(22) International Filing Date:</b> 2 October 1998 (02.10.98)  <b>(30) Priority Data:</b> 97117154.1                      2 October 1997 (02.10.97)                      EP 97117398.4                      8 October 1997 (08.10.97)                      EP 97119810.6                      12 November 1997 (12.11.97)                      EP  <b>(71) Applicants (for all designated States except US):</b> MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG DER WISSENSCHAFTEN E.V. [DE/DE]; Berlin (DE). NATIONAL PUBLIC HEALTH INSTITUTE [FI/FI]; Mannerheimintie 166, FIN-00300 Helsinki (FI).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> PELTONEN, Leena [FI/US]; 1029 Westholme Avenue, Los Angeles, CA 90024 (US). AALTONEN, Johanna-[FI/FI]; Näyttelijäntie 18 B 22, FIN-00400 Helsinki (FI). BJÖRSES, Petra [FI/FI]; Tarkk'ampujankatu 12 A 6, FIN-00150 Helsinki (FI). PERHEENTUPA, Jaakko [FI/FI]; Merikatu 3 A 2, FIN-00140 Helsinki (FI). PALOTIE, Aarno [FI/US]; 1029 Westholme Avenue, Los Angeles, CA 90024 (US). HORELLI-KUITUNEN, Nina [FI/FI]; Lauri Mikon-		pojan tie 12 C, FIN-00840 Helsinki (FI). YASPO, Marie-Laure [FR/DE]; Moltkestrasse 41, D-12203 Berlin (DE). LEHRACH, Hans [AT/DE]; Lützelsteiner Weg 50, D-14195 Berlin (DE).  <b>(74) Agent:</b> VOSSIUS & PARTNER; Siebertstrasse 4, D-81675 München (DE).  <b>(81) Designated States:</b> CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>  <b>(88) Date of publication of the international search report:</b> 24 June 1999 (24.06.99)
<b>(54) Title:</b> NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)		
<b>(57) Abstract</b> <p>The present invention relates to a nucleic acid molecule encoding a (poly)peptide co-segregating in mutated form with Autoimmune Polyendocrinopathy Candidiasis Ectodermal Dystrophy (APECED). In addition, the invention relates to a mammalian, preferably murine, homologue of the above nucleic acid molecule. The present invention further relates to a nucleic acid molecule deviating by at least one mutation from the nucleic acid molecule described above wherein said mutation co-segregates with APECED and is an insertion, a deletion, a substitution and/or an inversion, and wherein said mutation further results in a loss or a gain of function of the (poly)peptide encoded by said mutated nucleic acid molecule. Furthermore, the present invention relates to a vector comprising the nucleic acid molecules described above and to a host transformed with said vector. In addition, the present invention relates to a process of recombinantly producing a (poly)peptide encoded by the nucleic acid molecules described above comprising culturing or raising said host and isolating said (poly)peptide from said culture or said host. The present invention further relates to the (poly)peptide encoded by said nucleic acid molecules or produced by the process described above. Additionally, the present invention relates to an antibody that specifically recognizes said (poly)peptides. Moreover, the present invention relates to a method for testing for a carriership for APECED or for a corresponding disease state comprising testing a sample obtained from a prospective patient or from a person suspected of carrying a predisposition for a mutation in the wild-type nucleic acid molecule described above or a mutated form of the (poly)peptide encoded by said mutated nucleic acid molecule in an immuno-assay using the antibody described above.</p>		

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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 98/06294

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/12 C07K14/47 A61K38/17 A61K39/395 G01N33/68  
C12Q1/68 C07K16/18 A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C07K C12N A61K G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	LE DOUARIN B ET AL.: "The N-terminal part of TIF1, a putative mediator of the ligand-dependent activation function (AF-2), is fused to B-raf in the oncogenic protein T18" EMBO JOURNAL, vol. 14, no. 9, May 1995, pages 2020-2033, XP002098775 see the whole document --- -/--	1-7, 11-23,25

☒ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

### \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

1 April 1999

Date of mailing of the international search report

22/04/1999

Name and mailing address of the ISA

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Authorized officer

Oderwald, H

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 98/06294

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>LEVANON D ET AL.: "Common promoter features in human and mouse liver type phosphofructokinase gene"</p> <p>BIOCHEMISTRY AND MOLECULAR BIOLOGY INTERNATIONAL,</p> <p>vol. 35, no. 5, April 1995, pages 929-936, XP002098776</p> <p>cited in the application</p> <p>see the whole document</p> <p>&amp; LEVANON D ET AL.: "Accession number X80853"</p> <p>EMBL SEQUENCE DATABASE, 29 April 1996, Heidelberg, Germany</p> <p>see nucleotides 135-700</p> <p style="text-align: center;">---</p>	<p>1,4,5, 13-23,25</p>
A	<p>AALTONEN J ET AL: "AN AUTOSOMAL LOCUS CAUSING AUTOIMMUNE DISEASE: AUTOIMMUNE POLYGLANDULAR DISEASE TYPE 1 ASSIGNED TO CHROMOSOME 21"</p> <p>NATURE GENETICS,</p> <p>vol. 8, September 1994, pages 83-87, XP000673965</p> <p>cited in the application</p> <p>see the whole document</p> <p style="text-align: center;">---</p>	
P, X	<p>THE FINNISH-GERMAN APECED CONSORTIUM: "An autoimmune disease, APECED, caused by mutations in a novel gene featuring two PHD-type zinc-finger domains."</p> <p>NATURE GENETICS, (1997 DEC) 17 (4) 399-403. JOURNAL CODE: BRO. ISSN: 1061-4036., XP002098777</p> <p>see the whole document</p> <p style="text-align: center;">-----</p>	<p>1-23, 25-28</p>

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# INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 98/06294

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Remark: Although claim 28  
is directed to a method of treatment of the human/animal  
body, the search has been carried out and based on the alleged  
effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such  
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all  
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment  
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report  
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is  
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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